REMARKS

A final Office Action was mailed October 16, 2002, in which claims 39-60 were rejected and claims 62 and 63 were allowed. A Notice of Appeal was filed by Applicant on January 10, 2003. An interview with Examiners Liu and Kifle, inventor Matthew Platz and the undersigned was conducted on January 28, 2003. In the interview, it was indicated that claims drawn to a composition of water-soluble compounds and a blood product would be considered favorably.

In the final Office Action mailed October 16, 2002, claims 1-38 were withdrawn from consideration. Claims 39-60 were rejected under 35 U.S.C. 112, first paragraph. Claims 39 and 60 were rejected under 35 U.S.C. 112, second paragraph. Claims 39-59 were rejected under 35 U.S.C. 103(a) over Spencer (U.S. 3,920,650) and Petering (U.S. 2,825,729).

Amendments

This Amendment cancels claim 60 without prejudice and amends independent claim 39 to recite a composition comprising a member selected from the group consisting of biologically active protein, blood, and blood constituents and a water-soluble blood product additive photosensitizer. The proviso that R1 is neither H nor -OH nor a straight chain alkyl group where the second carbon of the chain is substituted with -OH or =O, (except for the two exemplified compounds) remains in claim 39. The other provisos in the claim have been removed, as discussed in the Interview. Claim 39 has also been amended for clarity by amending the Markush language and clarifying the substituents having optional substitution. Support for the added substituents is found in the specification on page 15, lines 13-16.

The amendment to include water-soluble compounds is supported by the specification and claims as originally filed, including page 12, line 6 through page 13, line 4, and page 13, lines 5 through 17. No new matter is added by any amendment, and all amendments are supported by the specification as filed.

35 U.S.C. 112, first paragraph rejections

In the Office Action mailed October 16, 2002, claims 39-60 were rejected under 35 U.S.C. 112, first paragraph. The metes and bounds of the terms "straight chain or cyclic saccharides", "amino acid groups", and "alkylating agents" were said to be unclear. In response, it is noted that the term "straight chain or cyclic saccharides" in independent claim 39 is limited to those straight chain or cyclic saccharides containing five or six carbon atoms, as recited on page 20, lines 22-23. A list of amino acid groups is recited in the specification on pages 19-20 and, as such, the metes and bounds of the term "amino acid groups" are believed defined. The term "alkylating agent" is believed to be recited only in claim 60. Claim 60 has been cancelled without prejudice.

The Office Action states: "applicants have not provided adequate information that the instant compounds as an entire class have the required activities needed to practice the invention." In response, it is believed Applicants have provided adequate information, in the form of evidence presented in response to the Office Action mailed March 21, 2002. In addition, MPEP 2164.04 indicates the burden is on the Examiner to establish a reasonable basis to question the enablement provided for the claimed invention (*In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)) and explain why the Patent Office doubts the truth or accuracy of any statement and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement (*In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). The Examiner has not provided such evidence.

The Office Action continues "Markush claims are subject to rejection based upon the lack of supporting disclosure when the 'working examples' fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms." In response, it is noted additional information regarding synthesis of claimed compounds was provided in the response to the Office Action mailed March 21, 2002.

Claims 39-60 were rejected under 35 U.S.C. 112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention. Provisos have been included in the claim. The provisos lack description." In response, the provisos added in response to the Office Action mailed March 21, 2002 have been deleted from the claim. It is believed this amendment obviates the rejection.

35 U.S.C. 112, second paragraph rejection of claim 60 and claim 39

Claim 60 was rejected under 35 U.S.C. 112, second paragraph for the term "alkylating agent". In response, claim 60 has been cancelled without prejudice. It is believed the cancellation of claim 60 obviates the rejection.

Claim 39 was rejected under 35 U.S.C. 112, second paragraph for the term "a component" and "optionally substituted". The term "a component" is used in conjunction with a Markush grouping in claim 39. In response, claim 39 has been amended to use alternative Markush language. In addition, the substituents which are optionally substituted have been specifically listed in claim 39. These amendments are believed to overcome the rejection.

35 U.S.C. 103(a) rejections

Claims 39-59 were rejected under 35 U.S.C. 103(a) over Spencer (US 3,920,650) and Petering (US 2,825,729). The Office Action states "Applicants' amended claims recite a composition comprising a component of a biologically active protein and the isoalloxazine compound. Spencer teaches the use of the isoalloxazine compound as antibacterial agents, the process of which involves the formation of a composition of the isoalloxazine compound and the bacteria which contain biologically active protein, including protein the bacteria could secrete into the surrounding environment." The Office Action states claims 39-59 were rejected under 35 U.S.C. 103(a) over Petering (US 2,825,729) for the same reasons given above.

In response, it is noted that the definition of "biologically active" in the specification on page 22, lines 17-19 states " 'biologically active' with respect to 'biologically active protein' as referred to herein does not refer to proteins which are part of the microorganisms being neutralized." Therefore,

by definition, the protein that the bacteria of Spencer could secrete is not included in the definition of biologically active in the claims and the claims are not obvious over Spencer. Petering does not discuss any inactivation of microorganisms and it is recalled from the arguments submitted in response to the Office Action mailed March 21, 2002 that Petering teaches away from the use of the disclosed compounds as blood additive photosensitizers, an activity shared with riboflavin, since Petering teaches that the compounds are riboflavin antagonists (Petering, column 1, lines 64-65).

In addition to the arguments given herein and in the response to the Office Action mailed March 21, 2002 which arguments are hereby incorporated, the amendment of the claims to include a water soluble blood product additive photosensitizer is believed to overcome the rejection as discussed in the Interview conducted on January 28, 2003. Neither Spencer nor Petering disclose or suggest water soluble compounds.

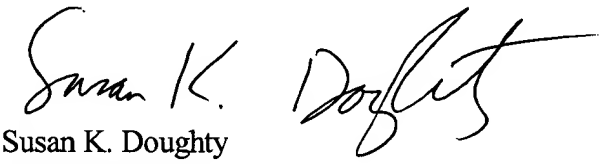
In view of the above arguments and amendments, it is believed the rejections under 35 U.S.C. 103(a) are overcome.

CONCLUSION

In view of the above amendments, it is believed claims 39-59 and 62-63 are allowable. Reconsideration and withdrawal of the rejections is respectfully requested. If there are any issues remaining to issuance, the Examiner is respectfully requested to telephone the undersigned.

This response is accompanied by a Request for Continued Examination and a check in the amount of $860.00 which includes the fee for a Request for Continued Examination. This response is also accompanied by a Petition for Extension of Time (one month) and the fee due for a large entity. If the amount submitted is incorrect, however, please charge any fee due or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



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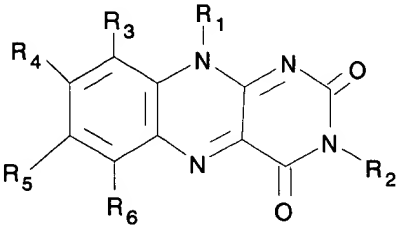
Version with markings to show changes made:

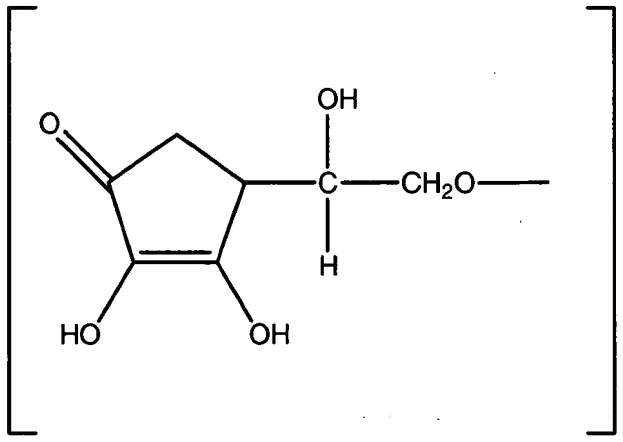
39. (Twice amended) A non-toxic composition comprising:

(a) a member [component] selected from the group consisting of biologically active protein, blood, and blood constituents; and

(b) a water soluble blood product additive photosensitizer for inactivating microorganisms suitable for administration to a patient having the structure:

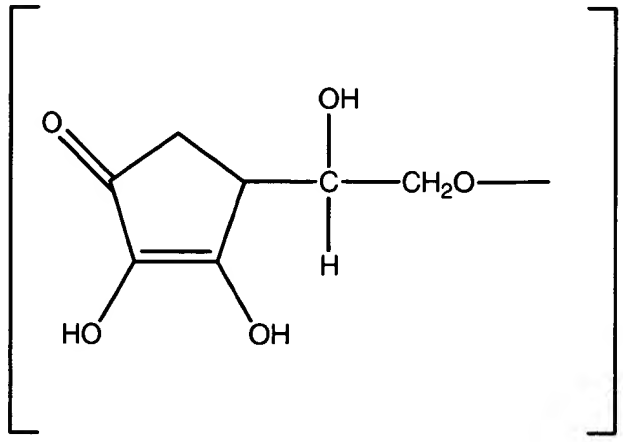


wherein R1, R2, R3, R4, R5 and R6 are, independently from one another, selected from the group consisting of hydrogen; -OH; -NH_2; -SO_4; -PO_4; -Cl; -Br; -I; straight chain or cyclic saccharides with 5 or 6 carbon atoms; ascorbate;



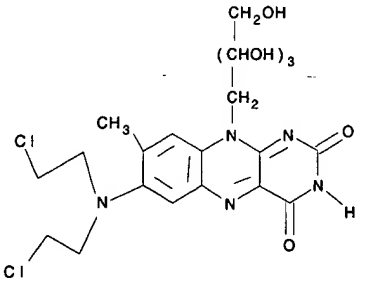
amino acid groups; optionally substituted alkyl, alkenyl, alkynyl or aryl groups with from 1 to 20

carbon atoms said alkyl, alkenyl, alkynyl or aryl groups optionally substituted with one or more of -O-, -S-, -OH, -SH, -COH, $-CO_2H$, $-NH_2$, $-SO_4$, $-PO_4$, -F, -Cl, -Br, -I; and $-NR^a-(CR^bR^c)_n-X$ wherein n is an integer from 0 to 20, X is a halogen selected from the group consisting of chlorine, bromine and iodine, R^a, R^b and R^c are, independently of each other, selected from the group consisting of hydrogen; straight chain or cyclic saccharides with 5 or 6 carbon atoms; ascorbate;

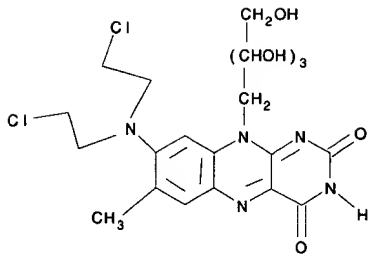


amino acid groups; optionally substituted alkyl, alkenyl, alkynyl or aryl groups with from 1 to 20 carbon atoms said alkyl, alkenyl, alkynyl or aryl groups optionally substituted with one or more of -O-, -S-, -OH, -SH, -COH, $-CO_2H$, $-NH_2$, $-SO_4$, $-PO_4$, -F, -Cl, -Br, -I; [and halogen selected from the group consisting of chlorine, bromine and iodine;] and salts of the foregoing [wherein n is an integer from 0 to 20];

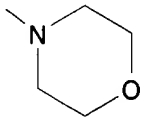
provided that R1 is neither H nor -OH nor a straight chain alkyl group where the second carbon of the chain is substituted with -OH or =O except that the compound may be



or

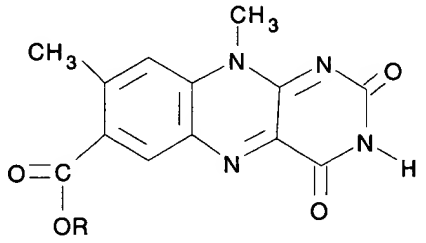


[and provided that R1, R4, R5 are not all methyl groups when R2, R3 and R6 are hydrogen and R1 is not a 2-, 3-, 4- or 5- carbon straight chain alkyl that terminates in -OH, -COH, or -H when R2, R3 and R6 are H, and R4 and R5 are CH_3; provided that R1 is not -OH or a straight chain alkyl group where the second carbon of the chain is substituted with -OH or =O; and R1 is not a 2-, 3-, 4- or 5- carbon straight chain alkyl that terminates in -OH, -COH, or -H when R2, R3 and R6 are H, and R4 and R5 are CH_3; R1 is not - CH_2CH_2-$(CHOH)_2$-CH_3 or -CH_2CH_2-$(CHOH)_2$ -CH_2SO_4 or 1'-D-sorbityl or 1'-D-dulcityl or 1'-D-rhamnityl or 1'-D,L-glyceryl or -CH_2-O-C(O)-CH_3 or -CH_2-O-C(O)-CH_2CH_3 or 2', 3', 4', 5'-di-O-isopropyridene-riboflavin or 8-aminooctyl when R2, R3 and R6 are H and R4 and R5 are CH_3; R1 is not 1'-D-sorbityl or 1'-D-dulcityl when R4 and R5 are both chlorines and when R2, R3 and R6 are all hydrogens; R5 is not ethyl or chloro when R1 and R4 are methyl and R2, R3 and R6 are all hydrogens; R4 and R5 are not both methoxy or both tetramethylene when R1 is methyl and R2, R3 and R6 are all hydrogens; R2 is not -CH_2CH_2NH when R1, R4 and R5 are CH_3 and R3 and R6 are H; R2 is not

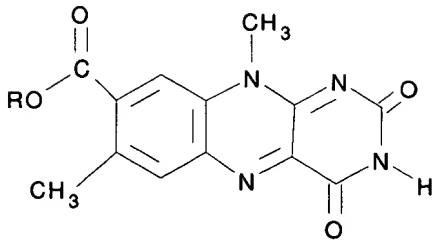


when R1, R4 and R5 are CH_3 and R3 and R6 are H; R5 is not chloro when R4 is methoxy and R1 is ethyl-2'N-pyrrolidino and R2, R3, and R6 are hydrogen; R1 is not N,N-dimethylaminopropyl or N,N-diethylaminoethyl when R5 is chloro or methyl and R2, R3, R4 and R6 are hydrogen; R3 is not -$NH(CH_2CH_2)Cl$ when R6 is -NH2 and R1, R2, R4 and R5 are H; R1, R4, R5 are not all methyl groups when all of R2, R3 and R6 are hydrogens; R1 and R2 are not both methyl groups when R3, R4, R5 and R6 are H; R1, R4, R5 and R2 are not all methyl groups when R3 and R6 are hydrogens; R2 does not contain a carbonyl group when R1, R4 and R5 are methyl and R3 and R6 are hydrogen; R4 is not -NH2 when R1 and R5 are methyl and R2, R3 and R6 are all hydrogen; R1 is not a phenyl group when R4 and R5 are methyl and R2, R3 and R6 are all H; R1 is not methyl or N,N-dimethylaminoethyl when all of R2, R3, R4, R5 and R6 are hydrogen; R2, R4, R5 are not all methyl when R1 is acetoxyethyl and R3 and R6 are hydrogen; R5 is not methyl when R1 is N,N-diethylaminoethyl and R2, R3, R4 and R6 are all hydrogen; R4 and R5 are not both chlorine when R1 is methyl and R2, R3 and R6 are all hydrogen; R1 is not ethyl, β-chloroethyl, n-butyl, anilino, benzyl, phenyl, p-tolyl or p-anisyl when R5 is NH_2 and R2, R3, R4 and R6 are all hydrogen; and R4 is not chlorine when R1 is N,N-dimethylaminopropyl and R2, R3, R5 and R6 are all hydrogen;

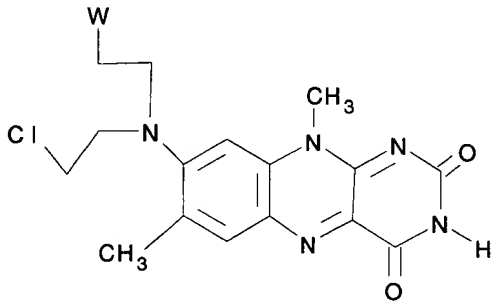
provided that the compound is not:



wherein R is selected from the group consisting of hydrogen and optionally substituted straight chain or branched alkyl having from 1 to 20 carbon atoms; and provided that the compound is not:



wherein R is selected from the group consisting of hydrogen and optionally substituted straight chain or branched alkyl having from 1 to 20 carbon atoms; and provided that the compound is not:



wherein W is a water soluble group; and provided that R4 is not -OH, -Br, -Cl, -SH, -O-Alk, or -SAlk when R5 is CH3; R6, R3 and R2 are H and when R1 is Alk or H, where Alk is an alkyl chain of 1 to 4 carbon atoms; provided that R2 is not a 11 carbon straight chain alkyl group when R1, R3, R6 are H and R4 and R5 are methyl; and provided that R2 is not octadecyl or undecyl when R4 and R5 are methyl and R3 and R6 are hydrogen; and provided that R2 is not a benzyl group when R1, R4 and R5 are methyl; and R3 and R6 are hydrogen; and provided that R1 or R2 do not contain a poly(pyrrolecarboxaminde) group; and provided that R5 is not bromo, chloro, nitro or trifluoromethyl when R2 is hydrogen, methyl, hydroxyethyl or benzyl and R3 and R6 are hydrogen and R1 is ethyl, propyl, isopropyl, butyl, pentyl, hexyl, phenyl, benzyl, phenehtyl, naphthyl, p-tolyl, p-ethylphenyl, p-anisyl, p-ethoxyphenyl, p-butoxyphenyl, 3,4-dicholorophenyl, methoxyethyl or ethoxyethyl; and provided that R1 is not a five carbon alkyl chain where four carbons are substituted with -O-COR

where RCO is a straight chain alkanoyl group containing from 4 to 20 carbon atoms; and provided that R1 is not a phosphoric acid substituted hydroxyalkyl group when R2, R3, R4, R5 and R6 are hydrogen; and provided that R1 is not a two to six member alkyl chain terminated with a sulfate radical, a phosphate radical or an acyloxy radical, the acyl group of which is derived from an organic acid with not more than eighteen carbon atoms].